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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MCDONNELL BOEHNEN HULBERT @ BERGHOFF LLP
300 SOUTH WACKER DRIVE
SUITE 3100
CHICAGO, IL 60606

EXAMINER	
BERTOGLIO, VALARIE E	

ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,021	FRANCIS-LANG ET AL.	
	Examiner	Art Unit	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5 and 16-17, drawn to an in vitro method of identifying CHK pathway modulating agents comprising an assay system wherein the primary assay system is a kinase assay.

Group II, claim(s) 1-4 and 6 and 16-17, drawn to an in vitro method of identifying CHK pathway modulating agents comprising an assay system wherein the primary assay system is an apoptosis assay.

Group III, claim(s) 1-4 and 6 and 16-17, drawn to an in vitro method of identifying CHK pathway modulating agents comprising an assay system wherein the primary assay system is a cell proliferation assay.

Group IV, claim(s) 1-4 and 6 and 16-17, drawn to an in vitro method of identifying CHK pathway modulating agents comprising an assay system wherein the primary assay system is an angiogenesis assay.

Group V, claim(s) 1-4 and 6 and 16-17, drawn to an in vitro method of identifying CHK pathway modulating agents comprising an assay system wherein the primary assay system is a hypoxic induction assay.

Group VI, claim(s) 1-4 and 7 and 16-17, drawn to an in vitro method of identifying CHK pathway modulating agents comprising an assay system wherein the primary assay system is a binding assay.

Group VII, claim(s) 1-4 and 8-10 and 16-17, drawn to an in vitro method of identifying CHK pathway modulating agents comprising an assay system wherein the primary assay system is an expression assay.

Group VIII, claim(s) 1,4-5, and 16,18,19 drawn to an in vivo method of identifying CHK pathway modulating agents comprising an assay system wherein the primary assay system is a kinase assay.

Group IX, claim(s) 1,4 and 6 and 16,18,19, drawn to an in vivo method of identifying CHK pathway modulating agents comprising an assay system wherein the primary assay system is an apoptosis assay.

Group X, claim(s) 1,4 and 6 and 16,18,19, drawn to an in vivo method of identifying CHK pathway modulating agents comprising an assay system wherein the primary assay system is a cell proliferation assay.

Group XI, claim(s) 1,4 and 6 and 16,18,19, drawn to an in vivo method of identifying CHK pathway modulating agents comprising an assay system wherein the primary assay system is an angiogenesis assay.

Group XII, claim(s) 1,4 and 6 and 16,18,19, drawn to an in vivo method of identifying CHK pathway modulating agents comprising an assay system wherein the primary assay system is a hypoxic induction assay.

Group XIII, claim(s) 1,4 and 7 and 16,18,19, drawn to an in vivo method of identifying CHK pathway modulating agents comprising an assay system wherein the primary assay system is a binding assay.

Group XIV, claim(s) 1,4 and 8-10 and 16,18,19, drawn to an in vivo method of identifying CHK pathway modulating agents comprising an assay system wherein the primary assay system is an expression assay.

Group XV, claim(s) 11, drawn to a method of administering a candidate CHK pathway modulating agent to an in vitro model system and comparing to a CHK deficient system to determining if CHK function is restored.

Group XVI, claim(s) 11 and 12, drawn to a method of administering a candidate CHK pathway modulating agent to an in vivo model system and comparing to a CHK deficient system to determining if CHK function is restored.

Group XVII, claim(s) 13 and 15, drawn to an in vitro method of modulating the CHK pathway by restoring CHK function using a modulator that binds to PAK.

Group XVIII, claim(s) 13-15, drawn to an in vivo method of modulating the CHK pathway by restoring CHK function using a small molecule modulator that binds to PAK.

Group IX, claim(s) 13 and 15, drawn to an in vivo method of modulating the CHK pathway by restoring CHK function using an antibody modulator that binds to PAK.

Group XX, claim(s) 20 and 22, drawn to an in vitro method of modulating CHK pathway in vitro.

Group XXI, claim(s) 20-22, drawn to an in vivo method of modulating CHK pathway agents using a small molecule.

Group XXII, claim(s) 20-22, drawn to an in vivo method of modulating CHK pathway agents using a nucleic acid.

Group XIII, claim(s) 20-22, drawn to an in vivo method of modulating CHK pathway agents using an antibody.

Group XXIV, claim(s) s 23-25, drawn to a method of diagnosing disease in a patient.

The inventions listed as Groups I-XXIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

PCT Rule 13.2 requires that unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-XXIV do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The "special technical feature" of Group I is PAK which is shown by Sells (Current Biology, 1997) to lack novelty or inventive step and does not make a contribution over the prior art.

Additionally, the inventions listed as Groups I-XXIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Unity of invention between different categories of inventions will only be found to exist if the specific combinations of inventions are present. Those combinations include:

1) A product and a special process of manufacture of said product.

2) A product and a process of use of said product.

3) A product, a special process of manufacture of said product, and a process of use of said product.

4) A process and an apparatus specially designed to carry out said process.

5) A product, a special process of manufacture of said product, and an apparatus specially designed to carry out said process.

The allowed combinations do not include multiple products, multiple methods of using said products, and methods of making multiple products as claimed in the instant application, see MPEP § 1850. Groups I-XXIV represent different methods requiring different starting products and different method steps to practice the method. With respect to the various in vitro methods, the assay used differs in method steps and technical considerations. With respect to the in vivo methods, the assay used differs

in method steps and technical considerations and, as well, the type of modulator differs, which require additional methodology and consideration with respect to how to administer such agents as a small molecule, a nucleic acid or an antibody to an animal in vivo.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Valarie Bertoglio, Ph.D./
Primary Examiner
Art Unit 1632